



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2023¹
EMA/PRAC/103894/2023
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 13-16 March 2023 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found [here](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Propofol – Medication errors that could potentially lead to life-threatening/fatal cases (EPITT no 19851)

Outer and immediate packaging

"For single use in one patient. Risk of sepsis in multiple use"

"Use immediately after opening"

2. Voriconazole; flucloxacillin – Drug interaction with flucloxacillin leading to subtherapeutic voriconazole levels (EPITT no 19849)

Voriconazole-containing products

Summary of product characteristics

4.5 Interaction with other medicinal products and other forms of interaction

¹ Expected publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



Medicinal product [Mechanism of interaction]	Interaction Geometric mean changes (%)	Recommendations concerning coadministration
...		
<u>Flucloxacillin</u> [CYP450 inducer]	<u>Significantly decreased plasma voriconazole concentrations have been reported.</u>	<u>If concomitant administration of voriconazole with flucloxacillin cannot be avoided, monitor for potential loss of voriconazole effectiveness (e.g. by therapeutic drug monitoring); increasing the dose of voriconazole may be needed.</u>

Package leaflet

2. What you need to know before you take <product>

Other medicines and <product>

Tell your doctor if you are taking any of the following medicines, as a dose adjustment or monitoring may be required to check that the medicines and/or <product> are still having the desired effect:

- ...
- Flucloxacillin (antibiotic used against bacterial infections)

Flucloxacillin-containing products

Summary of product characteristics

4.5 Interaction with other medicinal products and other forms of interaction

Flucloxacillin (CYP450 inducer) has been reported to significantly decrease plasma voriconazole concentrations. If concomitant administration of flucloxacillin with voriconazole cannot be avoided, monitor for potential loss of voriconazole effectiveness (e.g. by therapeutic drug monitoring); increasing the dose of voriconazole may be needed.

Package leaflet

2. What you need to know before you take <product>

Other medicines and <product>

Tell your doctor or pharmacist before taking this medicine if you are taking any other medicines:

- ...
- Voriconazole (used against fungal infections)